

117TH CONGRESS  
1ST SESSION

# H. R. 5435

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a Neuroscience Center of Excellence and a Neuroscience Translation Working Group, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 30, 2021

Mr. BLUMENAUER (for himself, Mr. PASCRELL, and Mr. BACON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a Neuroscience Center of Excellence and a Neuroscience Translation Working Group, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Bringing Regulatory  
5       Advances Into Neuroscience Act of 2021” or the “BRAIN  
6       Act of 2021”.

1   **SEC. 2. FINDINGS.**

2       Congress finds the following:

3           (1) The brain and central nervous system make  
4       up the body's most complex organ system.

5           (2) Nearly one in five adults in the United  
6       States (more than 50 million) live with a mental ill-  
7       ness, disproportionately impacting women, people re-  
8       porting two or more races, and individuals under age  
9       fifty.

10          (3) Neuropsychiatric disorders are the leading  
11       cause of disability in the Nation, making up 18.7  
12       percent of years lost to disability and premature  
13       death.

14          (4) Brain disorders, injuries, and diseases are  
15       estimated to cost the United States more than \$1.5  
16       trillion per year.

17          (5) Mental health and substance use disorder  
18       treatment spending is expected to total \$280.5 bil-  
19       lion in 2020.

20          (6) The SARS-CoV-2 virus can cause serious  
21       psychiatric and neurologic effects and the COVID-  
22       19 pandemic has exacerbated the burden of brain  
23       and central nervous system conditions.

24          (7) Products targeting the brain and central  
25       nervous system, including those conditions with few  
26       or no approved treatments, take longer to develop

1 and are less likely to be approved than products for  
2 other disease areas.

3 **SEC. 3. INSTITUTE AND ADVISORY COMMITTEE FOR DIS-**  
4 **EASES AFFECTING THE BRAIN OR CENTRAL**  
5 **NERVOUS SYSTEM.**

6 (a) **ESTABLISHMENT OF NEUROSCIENCE CENTER OF**  
7 **EXCELLENCE.**—Section 1014 of the Federal Food, Drug,  
8 and Cosmetic Act (21 U.S.C. 399g) is amended by adding  
9 at the end the following:

10 “(e) **NEUROSCIENCE CENTER OF EXCELLENCE.**—  
11 “(1) **IN GENERAL.**—The Secretary shall estab-  
12 lish an institute under subsection (a) to be known as  
13 the Neuroscience Center of Excellence to carry out  
14 activities under such subsection with respect to a  
15 major disease area or areas affecting the brain or  
16 central nervous system.

17 “(2) **AUTHORIZATION OF APPROPRIATIONS.**—  
18 There are authorized to be appropriated to carry out  
19 this subsection \$25,000,000 for each of fiscal years  
20 2023 through 2027.”.

21 (b) **NEUROSCIENCE TRANSLATION WORKING**  
22 **GROUP.**—Chapter X of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 391 et seq.) is amended by adding  
24 at the end the following:

1   **“SEC. 1015. NEUROSCIENCE TRANSLATION WORKING**2                   **GROUP.**

3         “(a) ESTABLISHMENT.—The Secretary shall establish  
4         and maintain an advisory board to be known as the  
5         Neuroscience Translation Working Group to advise the  
6         Director of the Neuroscience Center of Excellence under  
7         section 1014(e) (or the Commissioner of Food and Drugs  
8         in accordance with subsection (c)) on the following:

9                 “(1) Issues with respect to translating neuroscience  
10          discoveries to approved treatments for diseases and conditions affecting the brain or central  
11          nervous system.

13                 “(2) Activities to increase the translation of neuroscience discoveries to such approved treatments.

16                 “(3) The development of guidance with respect to diseases and conditions affecting the brain or central nervous system.

19                 “(4) Funding, collaboration, and other opportunities within the National Institute of Neurological Disorders and Stroke, National Center for Advancing Translational Sciences, or other Government entities to increase the translation of neuroscience discoveries to such approved treatments.

1               “(5) The incorporation of patient preferences,  
2               patient-reported outcomes, and real-world data in  
3               the development of regulations.

4               “(b) MEMBERSHIP.—The Neuroscience Translation  
5 Working Group shall consist of not more than eight mem-  
6 bers, including—

7               “(1) the Director of the National Institute of  
8 Neurological Disorders and Stroke (or designee);

9               “(2) the Director of the National Center for  
10 Advancing Translational Sciences (or designee);

11               “(3) three representatives from patient advo-  
12 cacy or national organizations that focus on injuries,  
13 diseases, or disorders affecting the brain or central  
14 nervous system, including organizations that rep-  
15 resent service delivery for patients;

16               “(4) two experts with experience conducting  
17 clinical trials with respect to diseases and conditions  
18 affecting the brain or central nervous system; and

19               “(5) one expert with expertise in the regulation  
20 of drugs, devices, and biological products.

21               “(c) TERMINATION OF NEUROSCIENCE CENTER OF  
22 EXCELLENCE.—If the Secretary, pursuant to section  
23 1014(d), terminates the Neuroscience Center of Excel-  
24 lence under section 1014(e), the Neuroscience Translation

1 Working Group shall advise the Commissioner of Food  
2 and Drugs.”.

3 (c) APPLICABILITY.—Sections 1014(e) and 1015 of  
4 the Federal Food, Drug, and Cosmetic Act, as added by  
5 this section, shall apply on the date that is not later than  
6 one year after the date of the enactment of this Act.

